MAR 2 3 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (21CFR 807.92)

I. DATE PREPARED: 4/21/2008

II. SUBMITTER:

BRIT Systems, Inc.
1909 Hi-Line Dr.
Dallas, TX 75207

III. CONTACT PERSON:

Robert Murry
VP of Engineering
bob@brit.com
Phone: 214-630-0636
Fax: 214-630-1638

IV. DEVICE NAME:

Classification Name: Picture Archiving and Communications System (PACS)
Trade/Proprietary Name: BRIT PACS SYSTEMS

V. DEVICE CLASSIFICATION

Class II
CFR section: 892.2050
Product code: LLZ
Panel: Radiology

VI. PREDICATE DEVICES:

K062477
AMICAS Vision Series PACS
Class II
Decision Date: 10/27/2007

K041935
DR Systems PACS
Class II
Decision Date: 08/16/2004

VII. SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

BRIT Systems concludes that the intended use for the BRIT PACS Systems is the same as that of the predicate devices, and that the technological characteristics demonstrate that they are equivalent to the predicate device. A comparison of the technological characteristics of the predicate and legally marketed devices available has been performed.
Thus, this premarket notification has demonstrated substantial equivalence.

VIII. DEVICE DESCRIPTION AND INTENDED USE:

System Description:

BRIT PACS Systems provides custom, turn-key solutions for PACS and teleradiology based systems on the latest DICOM standards. Using PACS, medical images can be made available at multiple locations - virtually anywhere at any time. Modular components make BRIT's solutions flexible, upgradeable, and scaleable.

BRIT SCAN is a high-quality film digitization system that allows standard radiographs to be converted into electronic images for transmission to PACS and teleradiolgy systems. BRIT Scan allows the users to integrate standard radiographic studies, which are often used for comparison studies, into the PACS strategy.

BRIT Quality Workbench is a DICOM based application that runs on a PC and is used to provide patient demographic and image data quality control functions within the PACS system.

BRIT Roentgen RIS provides a hospital or clinic with automated tools to electronically schedule and manage patient exam information. The Roentgen RIS utilizes a web based client that provides referring physicians the added flexibility to instantly view and schedule their own patients' radiographic services. The Roentgen RIS also accesses the same database as BRIT'S PACS solution.

BRIT Roentgen Files is the main product for exam and report storage in a PACS environment. It runs a DICOM Server and Web Server plus a selection of the following applications, all using the same database.

- DICOM Archive
- Modality Worklist Server
- HL-7 Interface Engine
- Order Entry/Scheduling package

BRIT Viewing Workbenches offer different viewing applications to address the differing needs of the users.

BRIT Vision is a diagnostic reading workbench which provides radiologists and high-power users a fully configured 12-bit DICOM image viewing workstation.

BRIT Vision Mammography Module is an optional diagnostic module utilizing 5MP monitors that runs in the BRIT Vision medical image viewing workstation.

BRIT View is a clinical viewing workstation or diagnostic reading workbench which provides high quality image viewing and manipulation capabilities in a fully configured 12-bit DICOM workstation, for use in radiology or non-radiological area of the facility such as ER, Surgery, ICU, and other areas.

BRIT Lite is a viewing application that responds to the needs of healthcare organization that require access to images anywhere, anytime, but without the need for advanced visualization tools or large application on each workstation.

BRIT Roentgen Burner is a DICOM compliant automated solution for producing custom-labeled CD's and or DVD's that contain medical images plus BRIT's image viewing software. Radiological studies are sent to this device from any BRIT DICOM workstation on the network.

BRIT Roentgen Works is a workflow management service for radiologists to provide remote reading services for multiple health care facilities.

Indications for Use:

The BRIT PACS Systems is an image management system whose intended use is to provide (scaleable) DICOM compatible PACS solutions for hospital and related institutions/sites, which will archive/ distribute/ retrieve and display images and data from all hospital modalities (such as CR, CT, DR, MR, and other devices) and information systems. This also includes the display of structured reports and mammography images that have been created according to DICOM "For Presentation", and will include standard features and other Mammo tools. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammography images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

Application areas include imaging centers, radiologist central reading rooms, and any other locations where trained medical professionals would require access or desire patient images, demographic information, or other patient medical information captured in the system.

IX. SAFETY INFORMATION:

The BRIT PACS Systems has no patient contact and is utilized only by trained professionals. Trained professionals allow sufficient review to afford identification and intervention in the event of a malfunction have evaluated the output of the device. Patient data is limited to authorized individuals.

X. CONCLUSION:

BRIT PACS Systems believes sufficient information is included to reach a determination of substantial equivalence. We conclude that the subject device is as safe and effective including the component and accessory devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2009

Mr. Robert Murry
VP of QA/Engineering
BRIT Systems
1909 Hi Line Drive
DALLAS TX 75207

Re: K081168
Trade/Device Name: BRIT PACS Systems
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: February 18, 2009
Received: February 19, 2009

Dear Mr. Murry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K081168

MAR 2 3 2009

510(k) Number (if known): ~~N/A~~ K081168

Device Name: BRIT PACS Systems

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081168